46

STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2017-18)

SIXTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

PROMOTION AND COORDINATION OF BASIC, APPLIED AND OTHER RESEARCH IN AREAS RELATED TO THE PHARMACEUTICAL SECTOR

FORTY-SIXTH REPORT

LOK SABHA SECRETARIAT
NEW DELHI

July, 2018/ Ashadha, 1940 (Saka)

CC&F.No.46

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MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

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Presented to Lok Sabha on 19 July 2018

Laid in Rajya Sabha on 19 July 2018

LOK SABHA SECRETARIAT
NEW DELHI
July, 2018/ Ashadha, 1940 (Saka)

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COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS
(2017-18)
Shri Anandrao Adsul - Chairperson
MEMBERS
LOK SABHA

2. Shri George Baker
3. Smt. Anju Bala
4. Shri B.N. Chandrappa
5. Shri Pankaj Chaudhary
6. Shri Sankar Prasad Datta
7. Dr. Ratna De Nag
8. Smt. Veena Devi
9. Shri R.Dhruvanarayana
10. Shri Innocent
11. Prof. A Seetaram Naik #
12. Shri K. Ashok Kumar
13. Shri Chhedi Paswan
14. Smt. Kamla Devi Patle
15. Shri Rajendran S.
16. Dr. Kulamani Samal
17. Dr. Uma Saren
18. Dr. Krishna Pratap Singh
19. Shri Kirti Vardhan Singh
20. Smt. Rekha Arun Verma
21. Shri Sarfaraz Alam*

RAJYA SABHA

22. Shri Biswajit Daimary
23. Shri Prem Chand Gupta
24. Shri B.K. Hariprasad
25. Shri Ranvijay Singh Judev
26. Shri Sanjay Dattatraya Kakade
27. Dr. Sanjay Sinh
28. Shri Abdul Wahab
29. Shri Vijay Pal Singh Tomar @
30. Vacant^
31. Vacant^

SECRETARIAT

1. Shri V.K. Tripathi - Joint Secretary
2. Shri A.K. Srivastava - Director
3. Shri U.C. Bharadwaj - Deputy Secretary
4. Ms. Sonia Sankhla - Executive Assistant

 # Prof. A. Seetaram Naik MP, (LS) has been nominated as a Member of the Committee on Chemicals and Fertilizers w.e.f. 3.11.2017 vice Shri Kotha Prabhakar Reddy MP, (LS) who ceased to be a Member of the Committee on Chemicals and Fertilizers w.e.f. 3.11.2017
**Shri Sarfaraz Alam has been nominated as a Member of the Committee on Chemicals and Fertilizers w.e.f. 27.04.2018*
@ Shri Vijay Pal Singh Tomar has been nominated as a Member of the Committee on Chemicals and Fertilizers w.e.f. 02.06.2018
^Vacant vice Dr. Bhusan Lal Jangade due to his retirement from Rajya Sabha on 02.04.2018.
^Vacant vice Shri K. Parasaran due to his retirement from Rajya Sabha on 28.06.2018.

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2017-18) having been authorised by the Committee to submit the Report on their behalf, present this Forty-sixth Report 'Promotion and Coordination of basic, applied and other research in areas related to the Pharmaceutical Sector' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The subject 'Promotion and Coordination of basic, applied and other research in areas related to the Pharmaceutical Sector' had been taken up by the erstwhile Committee on Chemicals and Fertilizers (2016-17) for examination and report. The Committee visited NIPER-Mohali and NIPER-Hyderabad on 15 June and 13 July 2017 respectively for the purpose of examination of the subject. The Committee also had informal discussion with the representatives of cluster of pharmaceutical units located at Baddi, Himachal Pradesh on 15 June, 2017. As the examination of the subject could not be completed due to paucity of time during the term of the Committee (2016-17), the subject was again selected for examination and reporting by the Committee (2017-18). The Committee took oral evidence of the representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) and NIPERs on the subject at their sitting held on 11 April 2018.

3. The Report was considered and adopted by the Committee at their sitting held on 13 July, 2018.

4. The Committee wish to express their thanks to the officers of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for furnishing the written replies and other material/ information and for placing their views on the subject before the Committee.

5. The Committee also place on record their appreciation for the valuable assistance rendered to them by the officials of the Lok Sabha Secretariat attached to the Committee.

6. For facility of reference and convenience, the observations / recommendations of the Committee have been printed in bold letters at the end of the Report.

New Delhi;
18 July, 2018
27 Ashadha, 1940 (Saka)

Anandrao Adsul
Chairperson
Standing Committee on
Chemicals and Fertilizers

PART-I

CHAPTER – I

INTRODUCTION

India enjoys global leadership in Pharmaceutical sector in Generic medicines. India celebrates the achievements of both Public and Private Pharma Industry for their contribution in India's self-reliance on medicines. Exports are being made to most of the Countries of the world with a major share in regulated markets. Much of the credit goes to policy initiative in terms of Patent Act, 1970 which allowed process patents, enabling in transformation of India from medicine importing country to exporting country and to the entrepreneurship of pharmaceuticals industry. Currently the pharmaceuticals sector is contributing Rs.2 lakh crores annually to the Indian economy, with 50% from exports.

1.2 Pharmaceuticals sector is a multi-disciplinary and the research is spread across a large number of ministries / Departments viz., Department of Biotechnology, Department of Science and Technology, Council for Scientific and Industrial Research, Indian Council for Medical Research, Department of Health and Family Welfare, Ministry of Human Resource Development, Ministry of AYUSH, and others.

1.3 In 2008, a separate Department for Pharmaceuticals has been created with a mandate of policy, planning, development and regulation of Pharmaceuticals Industries excluding those specifically allotted to other departments. The items include the subject of examination (2nditem)-promotion and coordination of basic, applied and other research in areas related to the Pharmaceutical Sector. Thus assumes the importance of Promotion and Co-ordination of basic, applied and other research in areas related to the Pharmaceuticals Sector.

1.4 Pharmaceuticals sector is a knowledge intensive industry. India being signatory of WTO and TRIPS agreement, it moved from process patent regime to product patent regime. Thus the options before the nation are very limited rather only two, either to wait for 20 years for becoming patent medicines of the west to become off patent to manufacture by Indian companies or start drugs discovery especially for the diseases of current and future priority, in the country.

1.5 The patented medicines are very costly and not affordable to common population. Analysis of Indian domestic market suggests that patent medicines constitute less than 1% share, illustrating poor accessibility/ availability of latest innovative medicines in the face of growing non-communicable / life-style diseases like cancer because of affordability. This issue reiterates the urgency for India to have paradigm shift in its strategy to expand its leadership in Drug Discovery and Innovation after post-WTO, TRIPS regime. Any

investment in Drug discovery will also help in making India an Innovation based economy. It is with this vision that Government has set up NIPERs under NIPER Act, 1998.

(Ref: Pg No-1 of Background note)

1.6 The Department in its background note stated that they have commissioned a Detailed Project Report for Developing India as a Drug Discovery and Pharmaceutical Innovation Hub by Ernst & Young. The **Ernst & Young** has submitted its report. The report has been finalized in consultation with all the stakeholders. Second Phase of the Implementation Report is under consideration in the Department.

(Ref: Pg No-2 of Background Note)

1.7 The Committee desired the Department to furnish the major highlights of this report related to achievements, challenges and the way forward for Indian Pharmaceutical Sector in the field of drug discovery and pharmaceutical innovation hub as recommended by the Ernst &Young consultancy firm, the Department in its written note submitted as under:-

> "DPR submitted by Ernst & Young has highlighted that India has one of the fastest-growing pharmaceutical sectors in the world. India ranks 3rd in terms of volume productivity with 10% share of the global pharmaceutical market. It occupies 14th position by value accounting for 1.5% of the total pharmaceutical production by value across the globe. India Pharmaceutical Sector directly employs around 500,000 people. However, to achieve the desired goal, India has to overcome long hurdles. In short, it has been observed that India has emerged as a potent drug development service provider but not a key player in innovative product research. Indian bio-pharmaceutical companies' early stage/biology research and translational research capabilities and R&D funding are weak compared to global bio-pharmaceutical companies. Contribution of India academia to new drug research is not substantive; patents and publishing have not translated into licenses as alignment with private sector has been weak. Hence, DPR has recommended that the Department should revisit its vision and revise the targets set in terms of percentage share in the global R&D pipeline. The key enablers to achieve the target includes:-
>
> **(A) Human Resources**:
>
> i. Attract top scientific Indian talent residing abroad through talent acquisition and talent attraction programs.
> ii. Incentivize the role of private sector in attracting and creating jobs in the research and development domain
> iii. Tie up with select/Top Global Life Science Technology institutions for various research fellowship and exchange programs (Promote initiatives such as the recent Global initiative for Academic Network (GIAN) announced between India and US
> iv. Improve the quality of pharmacy and biotech courses offered at both UG, PG and Doctorate level to upgrade the skill set for drug discovery and clinical development
> v. Make PhDs in science disciplines and research & Development a more attractive career option in India

(B) Infrastructure:

vi. Create a model integrated national facility dedicated to drug discovery and development in PPP mode, in one of the key life sciences hubs
vii. Give industry access to advanced instrumentation and specialized facilities in public R&D labs, which may not be economically viable for individual companies to purchase.
viii. Create infrastructure for storing and importing essential drugs, reagents and biological samples
ix. Enable industry to undertake animal studies in a hassle free manner

(C) Funding Availability:

x. Promote venture capital/angel funds and incubators for funding innovative life sciences start – ups and companies

(D) Industry-Academia linkage:

xi. Create targeted programmes and funding mechanisms to promote linkages and mobility between industry and academia
xii. Promote commercialisation potential of research in public R&D labs

(E) Regulatory scenario:

xiii. Establish a robust institutional mechanism for inter-ministerial coordination
xiv. Introduce a zero tolerance policy for quality assurance of clinical trials
xv. Reduce regulatory complexity for new drug application and approval
xvi. Incentivise innovative R&D through tax credits "

(Ref: Reply to Q No-28)

CHAPTER – II

ROLE AND MANDATE OF THE DEPARTMENT OF PHARMACEUTICALS

While stating the role and mandate accorded with particular reference to basic/applied and other research activities in Pharmaceutical Sector, the Department of Pharmaceuticals stated that as per the Business Allocation of the Department of Pharmaceuticals, following activities are *inter-alia* mandated to be undertaken by the Department of Pharmaceuticals:-

- Promotion and co-ordination of basic, applied and other research in areas related to the Pharmaceutical sector.
- Medical Devices - Industry issues relating to promotion, production and manufacture; excluding those specifically allotted to other Departments.
- Education and training including high end research and grant of fellowships in India and abroad, exchange of information and technical guidance on all matters relating to pharmaceutical sector.
- International co-operation in pharmaceutical research, including work related to international conferences in related areas in India and abroad.
- Inter-sectoral coordination including coordination between organizations and Institutes under the Central and State Governments in areas related to the subjects entrusted to the Department.

2.2 The Department further furnished that the mandate bestowed on the Department does not incorporate research activities in developing biomedical/medical devices including biomedical material for medical equipment. There is no allocation of budget for research activity in developing biomedical devices.

(Ref: Reply to Q No-1)

2.3 While furnishing a brief note on the status of Indian Pharma Industry with special reference to contribution of domestic pharma industry in meeting the requirements of drugs in the country and the level of dependency on imported drugs and firms producing patented drugs and the steps being taken for import substitution through domestic production, the Department stated as under :-

"The Indian Pharmaceutical Industry, driven by knowledge, skills, low production costs and international quality products, has witnessed a robust growth from the production turnover of about Rs. 5000 crores in 1990 is estimated to be about Rs. 2,19,0755.00 Crores during the year 2016-17. Out of this, the share of exports are around 50%. Pharma Exports from the country have shown rapid growth during the past three years as depicted in the table below:-

Commodity Group	2014-15 Value (RsCrores)	2015-16 Value(RsCrores)	2016-17 Value(RsCrores)
Bulk Drugs, Drug Intermediates	1791.99	23515.55	22683.30
Drug Formulations, Biologicals	68557.74	82760.25	84934.88
Grand Total	90349.74	106275.80	107618.19

(Source: DGCIS Kolkata)

In comparison to the exports, the imports have been far less. The details of India's imports of Bulk Drugs, Drug intermediates and Drug formulations, Biologicals during last three years is as under:

Years	Total import(Rs. cr)
2014-15	29394.09
2015-16	31585.59
2016-17	29516.49

(Source: DGCIS Kolkata)

India is globally, the 3rd largest producer of medicines by volume and 14th in terms of value. The lower value is due to the fact that Indian medicines are amongst the lowest priced in the world. India exports to more than 200 countries in the world including highly regulated markets like U.S.A.

The success story in the pharmaceuticals sector is characterized by our strengths in:

(i) Low cost manufacturing;
(ii) Developed chemistry with proven track record in advanced chemistry capabilities; and
(iii) Low cost, qualified, English-speaking manpower.

The Indian Pharmaceuticals Industry is producing various therapeutic equivalents of many patented drugs. The country is however, importing some Active Pharmaceuticals Ingredients (API) used in the manufacture of some essential medicines. These imports are mostly done because of economic consideration.

The Government is committed to make India sufficiently self-reliant in end to end indigenous drug manufacturing by reducing the import dependence on drugs and to make Indian Pharma Industry globally competitive. The policies formulated by Government from time to time are made so that the country's dependence from imports are minimized and to give fillip to indigenous manufacturing. In this direction, the Government had on 28.01.2016 notified the withdrawal of exemption in customs duties which were earlier given to certain categories of drugs and bulk drugs to provide a boost to the domestic manufacturers. Besides, the government has removed bottlenecks in environment clearance etc. which the manufacturers are facing, in order to give a boost to domestic manufacturing of bulk drugs.

Further, the Department is operating a scheme viz. Cluster Development Scheme for Pharma Sector (CDP-PS) for financing common facilities in pharma cluster with the objective to enhance quality, productivity and innovative capabilities of the SME pharma sector in the country. Further, Department has prepared an umbrella scheme namely 'Scheme for Development of Pharmaceutical Industry' which has been approved by the Standing Finance Committee (SFC) in its meeting on 7.2.2018. The said umbrella scheme comprises of the following sub schemes :-

i. Assistance to Bulk Drug Industry for Common Facility Centre;
ii. Assistance to Medical Device Industry for Common Facility Centre;
iii. Assistance to Cluster Development;

iv. Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS);
v. Pharmaceutical Promotion and Development Scheme (PPDS).

It is expected that this scheme would help the Pharmaceutical industry including Bulk Drug and Medical Device Industry to cut down their production cost and also to upgrade their plants to WHO-GMP standards. This would help the patients to get quality medicines at affordable price."

(Ref: Reply to QNo-2)

2.4 On being asked about the details of imported generic medicine, the Department in its written note stated as under :-

"Pharmaceuticals products available in the market are sometimes referred to as generic, branded-generic and branded products etc. while no such distinction is made under Drugs and Cosmetics Act, 1940 and Rules, 1945. Branded and generic may be referred as under:

1. **Branded medicines:** A branded medicine is internationally referred to as the drug product of the originator under a brand name that was first authorized for marketing worldwide (normally as a patented product). The branded medicines are authorized for marketing on the basis of detailed documentation of its safety, efficacy and quality according to the requirement at the time of authorization.

2. **Generic medicines:** Generic medicines are those which contain same amount of same active ingredient(s) in same dosage form, and are intended to be administered by the same route of administration as that of branded medicine.

As and when application for import/ registration for import of finished formulations is received, the same is processed in accordance with the provisions of Drugs and Cosmetics Rules and import licence and registration certificate are issued. Since, January 2016 to till date more than 350 import licenses have been issued for import of various finished formulation of medicines into India."

(Ref: Reply to QNo-3)

2.5 While furnishing the steps that have been taken for the promotion and coordination of basic applied research in areas related to pharmaceutical sector and details of schemes implemented, the Department of Pharmaceuticals stated in a written note as under:-

"The Department has established seven NIPERs at Mohali, Ahmedabad, Hyderabad, Guwahati, Kolkata, Raebareli and Hajipur to promote basic and applied research catering to the needs of pharma industry. The Institutes impart postgraduate and doctorate education in pharmaceutical sector. The Institutes are provided with financial resources for construction, equipping of laboratories and payment of salaries, stipend to the students and recurring expenses."

(Ref: Reply to QNo-4)

2.6. With regard to details of focus areas for pharmaceutical industry and broad guidelines that are issued to stakeholder including NIPER for undertaking drugs research in the country and diseases for which at present there does not exist standardization and reliable drugs for treatment, the Department in its written note stated as under :-

> "NIPERs carry out research in the area of New Drug Discovery & Drug development in various therapeutic areas. The Institutes have linkages with industry and other research organizations to assist in this regard. NIPER Mohali is doing research in Tuberculosis, Kala Azar and various other diseases. NIPER Hyderabad is carrying out research in the areas of cancer, inflammation, diabetes and infectious diseases and is involved in Rational Drug Design and Synthesis of New Chemical Entities (NCEs), Bulk Drugs and Intermediates, Development of Analytical Methods, Solid state characterization and Novel Drug Delivery Systems viz., Conventional, Nano & Micro emulsion technologies. NIPER Ahmedabad is carrying out research in the areas of Diabetes, Cancer, Neurodegenerative Disease, Infectious diseases, Tissue repair, regeneration and Medical Implants. NIPER Raebareli is carrying out drug research in the areas of neurodegenerative disorders, Tuberculosis, and environmental toxins. NIPER Guwahati is involved in development of Biopharmaceuticals using Biomolecular Engineering/Synthetic Biology, investigation on Genomics and Proteomics to study various diseases and studies on the mitigation of drug induced toxicities through natural products derived from Northeast India, etc. NIPER Hajipur is involved in development of novel drugs against Kala azar (Leishmaniasis), development of non-invasive tool for early detection of breast cancer, development of Novel therapeutic strategies against HIV, etc. NIPER Kolkata is carrying out research in the areas of synthetic and plant based drug discovery, immunology and immune diagnostics, cellular and molecular biology,recombinant DNA technology and monoclonal antibody technology, novel drug delivery systems, chemical and biochemical process technology, etc."

(Ref: Reply to QNo-5)

2.7 Regarding periodical review of performance analysis of research institutions and the challenges ahead, the Department of Pharmaceuticals stated as under:-

> **"**Department reviews the progress of the research made by NIPERs in its periodical Steering Committee Meetings. The Institutes are peer reviewed. Further, NITI Aayog has recently evaluated the performance of existing NIPERs."

(Ref: Reply to QNo-6)

2.8 Further elaborating on the plan of action the Department is contemplating to provide enabling ecosystem for drugs Discovery and Innovation in pharma sector after post World Trade Organization (WTO) and Trade Related Aspects of Intellectual Property Rights (TRIPS) and the details of promotional efforts made and the budget allocated in this regard on annual basis, the Department in their written note stated as under:-

"The Government of India has made several efforts so that patent legislation in India on the one hand utilizes the TRIPS flexibilities to ensure that access to healthcare does not suffer and on the other hand provides an IP framework conducive to protection of bona-fide innovators. Subsequent to India becoming signatory to the TRIPS Agreement in 1995, Indian patent laws were amended to comply with TRIPS. The Patents Act, 1970 was amended in 2005, whereby provisions were brought in for bringing pharmaceuticals or medicines under the product patent regime with effect from 1st January, 2005. After the amendment in 2005, Indian companies have been filing for product and / or process patents.

The Department is implementing a Scheme for financing common facilities in pharma cluster to catalyse and encourage quality, productivity and innovation in Pharmaceutical sector and to enable the Indian Pharmaceutical industry to play a leading role in a competitive global market post World Trade Organization (WTO) and Trade related aspects of intellectual property rights (TRIPS)."

(Ref: Reply to QNo-7)

2.9 While elaborating on the possible fallout and consequences particularly with reference to affordability of medicines and export earning, in case, there is any policy paralysis or vacuum to take mandatory steps to honor WTO and TRIPS guidelines, the Department of Pharmaceuticals in their written note stated as under:-

"TRIPS establish minimum levels of protection that each government has to give to the intellectual property of fellow WTO members. In doing so, society benefits in the long term when intellectual property protection encourages creation and invention, especially when the period of protection expires and the creations and inventions enter the public domain. Under the TRIPS Agreement, WTO members have to provide patent protection for any invention, whether a product or process for at least 20 years from the date on which the patent application was filed. The same has been guaranteed under Section 48 read with Section 53 of the Patents Act, 1970. TRIPS Agreement allows policy space to countries to evolve a regime that best suits its condition. This policy space is a sine qua non for sustainable development of the country. India is a party to Doha Declaration on the TRIPS Agreement and Public Health which clarifies that TRIPS agreement does not and should not prevent members from taking measures to protect public health."

(Ref: Reply to QNo-8)

2.10 On being asked about the details of patents that have been filled by NIPERs so far, NIPER-wise and the role of IPR Cell of NIPER, the Department of Pharmaceuticals gave the following detail:-

NIPER	No. of patents filed
Mohali	186
Hyderabad	44
Ahmedabad	03
Guwahati	Nil

Hajipur	Nil
Raebareli	Nil
Kolkata	Nil

As on date, only NIPER Mohali has IPR Cell. It maintains database of patents and also helps inventors in drafting, filing and prosecution of patents. Scientists at IPR Cell are also involved in teaching of IPR related courses to increase awareness towards use and promotion of IPRs through seminars, quiz and other events."

(Ref: Reply to QNo-9)

2.11 The Committee further sought to know about the impact of Patent Amendment Act 2005 on R&D by drug industries. The Department in their written note stated that Indian companies need to take necessary approvals and licenses from the innovator companies for the manufacture and marketing of the patented drugs. However, post expiry of the patents the companies can produce the generic version of the same. The Indian Patent Act contains provisions for grant of compulsory licenses for the patented product to be produced and sold by the Indian Drug companies in case of emergency situation.

(Ref: Reply to QNo-10)

CHAPTER – III

PROMOTION OF RESEARCH & DEVELOPMENT ACTIVITIES

The Department of Pharmaceuticals has undertaken the following activities for Promotion and Co-ordination of Basic Research:-

(i) Budgetary allocation for research in the Department is very limited. The Department is supporting only 2 research projects viz., A Scheme of Rs.4.88 Crores on Target specific New Drug Discovery for Anti-Tubercular Agents projects and a Scheme of Rs.4.88 Crores on Target specific New Drug Discovery against Kala Azar. In the FY 2016-17, a budgetary allocation of Rs.2.44 Crores was made for each project. However, no fund was released during FY 2016-17 to NIPER Mohali as they did not utilize earlier fund already allocated. Therefore, no budgetary allocation has been made in current financial year. Moreover, the continuance of both schemes for a further period of two years with no additional fund is under consideration in the Department.

(ii) The Department has commissioned a Detailed Project Report for Developing India as a Drug Discovery and Pharma Innovation Hub by Ernst & Young. The E&Y has submitted its report. The report has been finalized in consultation with all the stakeholders. Second Phase of the Implementation Report is under consideration in the Department.

(iii) The Department has entrusted National Institute of Public Finance and Policy (NIPFP)to formulate a scheme on Venture Capital Scheme- to support startups in Drug Discovery and Innovation. The NIPFP is yet to submit the final report.

(iv) The Department is actively involved in the project approval under Dept.of Science and Technology Scheme: Drugs and Pharmaceuticals Research (DPR).

(v) NIPERs have undertaken 21Academia —Industry Linkage MOUs with leading pharma industries which include one each with 4 Pharma CPSEs i.e. Rajasthan Drugs and Pharmaceuticals Ltd(RDPL), Indian Drugs &Pharmaceuticals Limited(IDPL), Karnataka Antibiotics &Pharmaceuticals Limited(KAPL) and Hindustan Anti-biotic Limited(HAL) and 2 with Bengal Chemicals and Pharmaceuticals Limited(BCPL) and 15 leading Private Pharma Companies like Dr. Reddy's Labs, Bharat Biotech, NATCO, Cadila Pharmaceuticals, Cadila Healthcare (Zydus), Sahjanand Technologies, Johnson & Johnson, Sun Pharma, Wockahardt, Panacea Biotech and Medley Pharmaceuticals Ltd , Dow Chemical International Pvt. Ltd., Tirupati Medicare Ltd, Kwality Pharmaceuticals Ltd. and Celeste Life Science Pvt. Ltd. This is Pharma initiative to build Innovation Ecosystem in India.

(Ref: Pg No-2 of Background note)

3.2 In view of the above the Committee asked about the strategy of Department of Pharmaceuticals to facilitate Small and Medium Enterprises and other organization to promote their R&D activities which they are unable to do due to paucity of funds as well as lack of infrastructure and risk involved in research process, the Department in its written note stated

that in order to facilitate various Pharma & Medical Devices companies in the Private Sector to pursue collaborative research, NIPERs have signed MOUs with Industries, including SME to conduct collaborative research on specific topics.

(Ref: Reply to Q No-12)

Research and Development Activities by Small and Medium Enterprises

3.3 During a study visit of the Committee to NIPER Mohali in month of June 2017, NIPER Mohali submitted the following views regarding promotion and co-ordination of basic applied research in areas relating to Pharmaceutical sector.

> "The economics of the drug discovery process prevents many small-scale entrepreneurs, who may have practical, innovative ideas, from participating in it. A platform, containing the common facilities, needs to be provided to scientists within the country where the entire chain of drug discovery and development process can be carried out without the need for initial investment of capital budget. Further, a molecule moves along the drug development process before it falls off the pipeline, the higher is the investment that goes waste. It is an increasingly common practice among pharmaceutical giants to adopt translational research/medicine as a route to identify those novel molecules that are likely to survive this intensive process. This is especially important in predicting whether a drug molecule is likely to have low toxicity and survive clinical trials, right in the early stages of development. This will bridge the gap between pre-clinical and clinical stages, addressing the 'Phase II attrition' problem, thus reducing the cost of the process. To this end, multinational companies are increasingly turning eastwards to exploit the highly skilled manpower that is available here. Most of these efforts are concentrated in China and parts of East Asia. In order to become R&D hub in the drug discovery and development programme, India has to grab the opportunity in establishing itself as a centre of excellence via public-private partnership."

(Ref: Pg No-6 of LOP for interaction with DOP and NIPER Mohali)

Research and Development Activities By Pharmaceutical PSUs

3.4 When asked about the steps that are involved before a pharma R&D companies/institution gets approval for its new drug formulation and starts commercial production of the same and the constraints phased by Indian pharma Companies/institution in bringing new drug formulations, the Department in their written note stated as under:-

> **"**Once a Pharma company develops a new formulation or dosage form through its R&D efforts, approval under the Drugs & Cosmetic Act is mandatory to be obtained from the CDSCO as new drug. Such approval is accorded by the office of the Drug Controller General (India) DCG(I) after examining the relevant data provided by the company regarding safety and efficacy of the new formulation."

(Ref: Reply to Q No-13)

3.5 Bengal Chemicals and Pharmaceuticals Limited (BCPL) was producing Anti Snake Venom Serum earlier however, due to paucity of fund, the company has not been producing the same for the last 10 years and there are very limited suppliers like Biological E Ltd. & Vins Bioproducts Ltd., Hyderabad and Bharat Serum & Vaccines Ltd., Mumbai. But the supply made by them is insufficient as around 50,000 poor people are dying every year due to snake bite and about 2.5 lakh people snake bites are being reported every year.

(Ref:- Pg No-12 BCPL)

3.6 The Committee asked about the reasons of not providing funds to BCPL for the prestigious and precious Anti Snake Venom Project, the Department in its written note stated as under:-

> "Government of India had sanctioned a Revival Package to BCPL in the year 2006 for modernization of its plants and machineries. After receipt of the funds, BCPL started construction activities for the Anti Snake Venom Serum (ASVS) Project. However due to pending court case relating to the land, work could not proceed. The court case was vacated only in May, 2013. In the meanwhile, the Company had mismanaged the project and failed to achieve the targets given while sanctioning the Revival Package. Hence the Board of BCPL decided not to pursue further for the ASVS project and waste the Government funds.

Ref: Reply to Q No-14)

3.7 While giving details about the R&D activities carried out by the BCPL, the Company stated as following:-

> Company presently is not undertaking any R&D activities to improve its products. However, small activities are being done like signing of MoU with NIPER, Kolkata for developing/manufacture of ASVS (Anti Snake Venom Serum) products at Maniktala and another MoU with NIPER, Hajipur for development of Pantoprazole Tablet and Diclophecan Sodium Tablet. In this direction, Company is working with the research associates like NIPER to undertake some studies and suggest some measures to improve the efficiency and performance of the marketing team of BCPL. The measurable results will come only the future days after the Company becomes a turnaround company.
> However, the following major R&D activities have been taken in last three years:-
>
> (i) Labeling & Packing of Cantharidine hair oil 100 ml was changed to make it more attractive in market in competition with the leading brands in the market.
> (ii) Lamitube packing was introduced for newly launched pain relieving gel (Diclofenuc Gel, Trade name – Benflam) which is at par with the leading brands in the market. This lamitube is user friendly and aesthetically looks better than the convention aluminum tubes.
> (iii) Introduction of aqueous coating in film coated tablets in place of using non aqueous coating with organic solvent for last several years. This aqueous coating is cost affective, environmental friendly and less hazardous.

(Ref:- BCPL)

3.8 On being asked about the progress in respect of R&D activities of BCPL and how the Department of Pharmaceuticals is going cooperate them in view of its financial turnaround recently, the Department in its written note stated that the Cabinet has already decided in December, 2016 to strategically sell the company. Further steps are being taken to implement the Cabinet decision. The Company has since turned around and achieved net profit during the last two years. The Board of the Company can take a decision at its level to undertake R& D activities.

(Ref: Reply to Q No-15)

COORDINATION AMONG VARIOUS DEPARTMENTS AND LABORATORIES

3.9 R&D activities in Pharma sector is carried out by various governmental organizations like CSIR, ICMR, IIB, IICT, AIIMS, CDRI, IITs and pharmaceutical companies in public and private sector. Ministry of Defense, Department Of Atomic Energy also carry out R&D activities in the field of pharmaceutical & medical devices etc. NIPERs are major educational & research institutes who have collaboration with various organizations as well as public & private sector companies. For example, NIPER Kolkata has collaboration with BCPL for Anti Snake Venom Serum (ASVS). Similarly, NIPER Mohali have collaboration with various leading pharma companies like Cadila, Sun Pharma, Panacea Biotech, etc.

(Ref: Dictation by Dir)

3.10 The Department of Pharmaceuticals while furnishing the way it keeps tab on all the research carried out by the aforesaid organizations & companies and on mechanism developed to prevent overlapping of research work and coordinate R&D activities stated as under:-

> "The Department is regularly in contact with the Scientific Departments like DBT, DSIR, DST and other agencies/ Institutes engaged in the decision making processes about their scientific programs. Apart from this, NIPERs are interacting with various NIPERs and other Scientific Institutions of Central and State Government to have update about the research work being carried out at such laboratories in academia as well as the Industry."

(Ref: Reply to Q No-16)

3.11 On being asked about details on whether the Government is contemplating to integrate all the public Department/Organizations/Institutions already engaged in pharmaceutical activities including R&D to ensure requisite synergy to boost the R&D activities at one place for better administrative and financial management, the Department in its written note stated as under:-

> "Even though integration of various Departments/Organizations /Institutions already engaged in Pharmaceutical activities including R&D, is a Policy matter, the Department would like to at least have a mechanism in place to facilitate creation of a depository of R&D activities in the field of basic drugs, drug intermediates, Pharmaceutical formulation including Novel Drug Delivery Systems (NDDS), Medical Devices etc. so that duplication of research work could be avoided to the extent possible."

(Ref: Reply to Q No-17)

CHAPTER-IV

STATUS OF PHARMACEUTICAL RESEARCH IN NIPERs AND THEIR COMMERCIALIZATION

The Department in its background note stated that the premier higher institutions of education and research on Pharmaceuticals Sciences- National Institutes of Pharmaceutical Education and Research (NIPERs), though 7 NIPERs are operating, only one i.e. NIPER, Mohali is full-fledged with its own campus and sanctioned faculty, while all other NIPERs are running from temporary accommodation/mentor institutions for the last 8 years. Thus undertaking of research by contractual and adhoc faculty cannot be expected. Even at Mohali, the faculty is not at full sanctioned strength because of inadequate budgetary allocations.

(Ref: Pg No -3 of Background Note)

4.2 While submitting during oral evidence before the Committee on 11.04. 2018 the Secretary, Department of Pharmaceuticals clarified the role of NIPERs as under:

> *"....Like IIMs and IITs which offer Master of Technology courses and also do research work similarly NIPERs are educational institutes and not research labs. For pure research there are CSIR labs, National Physical Laboratory, National Chemical Laboratory, Bhabha Atomic Research Centre, NIPERs cannot be compared with these institutes because their job is to prepare students for post graduation courses in pharmacy and post graduation in research, so we cannot expect original research work from these institutes, that would be unfair and their work is to prepare the ground."*
>
> **(Ref: Verbatim Proceedings Pg No-29)**

(A) INFRASRUCTURE, GOVERNANCE AND HUMAN RESOURCE STATUS

4.3 While furnishing the details of main recommendations of the NITI Aayog on NIPERs and the steps the Department has taken or proposed to take to implement these recommendations, the Department in its written note stated as under:-

"The major recommendations of NITI Aayog include:

(i) Strengthening of existing NIPERs
(ii) Starting Undergraduate and other courses.
(iii) Filling up the post of Director.
(iv) Increasing the revenue generation.
(v) Vertical construction of building.
(vi) Putting in place facilities for drug discovery.

The recommendations of the Aayog were duly incorporated in the Expenditure Finance Committee (EFC) Memorandum and approval of Ministry of Finance obtained. Department has initiated action to implement the same."

(Ref: Reply to Q No-47)

4.4 Responding to a query of the Committee about the efforts taken/being taken by the Department to build independent campus for all NIPERs and ensure permanent faculty for

imparting quality research education to students, the Department in its written note stated as under:-

> "A meeting of EFC held under the chairmanship of Secretary, Expenditure, Ministry of Finance on 26.3.2018 has given its recommendations for providing infrastructure support, creation/ filling up of posts etc. Subsequent to approval of the EFC of NIPERs, construction of regular campuses of NIPER Ahmedabad/Guwahati will commence soon and action initiated for purchase of equipment and creation/ filling up of permanent jobs in NIPERs."

(Ref: Reply to Q No-38)

4.5 The Committee in their 18th Report (16th Lok Sabha) had observed that most of the NIPER Institutes lack state-of-the-art infrastructure for undertaking research work. Research infrastructure in NIPER, Mohali has become obsolete and needs comprehensive overhauling/innovation. In NIPER, Ahmedabad infrastructure i.e. laboratory, equipment etc., require augmentation and the same is the case in NIPER, Kolkata and NIPER, Raebareli where no research activity is being carried out.

4.6 While responding to the steps that are proposed to be taken by Department of Pharmaceuticals to contain the above infrastructure problems which are affecting Research & Development of NIPERs, the Department in its post evidence written note stated as under:-

> "EFC under the chairmanship of Secretary, Expenditure, Ministry of Finance has recommended that emphasis be given for setting up state-of-the-art-laboratory facilities at various NIPERs. Sufficient funds for the purpose have been proposed. Further creation of number of academic and non-academic posts at various NIPERs has been proposed.

(Ref: Reply to Q No-20)

4.7 Responding further about the efforts being taken by the Department to bridge the administrative deficiency since most of the NIPERs are functioning without their own Board of Governors and post of Directors are also vacant impacting the functioning of these institutes, the Department in its written note stated as under:-

> " Action is being taken to constitute the Board of Governors (BOG) of NIPERs (Mohali has its own BOG). In absence of BoG, a Steering Committee under chairmanship of Secretary, Pharmaceuticals look after administrative/financial matter of NIPERs. The posts of Directors in NIPERs Mohali, Kolkata, Guwahati, Gandhi Nagar and Raebareli have already been filled up. The posts of Directors, NIPERs Hajipur and Hyderabad are at final stages of filling up."

(Ref: Reply to Q No-46)

4.8 Further responding to the constraints that are being faced by NIPERs to accomplish the targets set under these MOUs, the Department in its written note stated as under:-

"Lack of permanent campuses, well equipped laboratories, permanent faculty and staff and insufficient funding are some of the constraints being faced by NIPERs to accomplish the set targets."

(Ref: Reply to Q No-32)

4.9 To a specific query regarding the steps that are being taken to stop attrition/brain drain due to lack of job security in NIPERs and to create permanent jobs for faculty as well as subject/technical experts in the NIPERs, the Department in its written note stated as under:-

"A meeting of EFC held under the chairmanship of Secretary, Expenditure, Ministry of Finance on 26.3.2018 has given its recommendations for providing infrastructure support, creation/ filling up of posts etc. Subsequent to approval of the EFC of NIPERs, action is being initiated for creation of academic and non-academic posts. Regular faculty will reduce the attrition/ brain drain."

(Ref: Reply to Q No-33)

4.10 During oral Evidence before the Committee on 11.04.2018, the Director NIPER-Hyderabad gave following views on problem of brain drain:-

"If people who work in NIPER can be absorbed in NIPER, the brain drain taking place in our country can be stopped. As on date the biggest problem we are facing in NIPER is good talent has left us...problem is we do have jobs for them but that is contractual..."

(Ref: Verbatim Proceeding Pg No-20)

(B) <u>FUND STATUS FOR RESEARCH & DEVELOPMENT ACTIVITIES</u>

4.11 The Department has entrusted National Institute of Public Finance and Policy (NIPFP) to formulate a scheme on Venture Capital Scheme- to support startups in Drug Discovery and Innovation. The NIPFP is yet to submit the final report.

(Ref: Pg No-2 of Background Note)

4.12 The Committee further asked about the steps taken for smooth implementation of venture capital scheme which will support startups in drug discovery and innovation and preparedness the Department has done in this regard to provide a trusted handholding to pharmaceutical start ups in India, the Department in its written note stated as under:-

"Ministry of Finance, Department of Expenditure vide their OM No. 24(35)/PF-II/2012 dated 5.08.2015 had instructed for rationalization of the schemes which are/to be implemented by various Ministries. Subsequent to these instructions, the Department has prepared an umbrella Scheme for Development of Pharmaceutical Industry wherein schemes including setting up of Venture Capital Fund for financing drug design, discovery & innovation in Pharmaceutical Sector have been dropped and Schemes for Assistance to Bulk drugs industry for Common Facilitation Centre, Assistance to Medical device Industry for Common Facilitation Centre, Cluster Development, Pharmaceuticals

Technology Up-gradation Assistance Scheme (PTUAS) and Pharmaceuticals Promotion Development Scheme (PPDS) are proposed to be taken up for promoting the growth of Pharmaceutical and Medical Device Industry."

(Ref: Reply to Q No-29)

4.13 The Department while furnishing NIPER-wise details of expenditure incurred, submitted following data as under:-

Funds released to NIPERs from 2012-13 to 2017-18

(Rs. in crore)

Year	**Ahmedabad**		**Guwahati**		**Hajipur**		**Mohali**	
	Gen	Cap.	Gen	Cap	Gen	Cap	Gen + Salary	CCA
2012-13	4.13	2.57	2.00	3.22	0.45	0.00	22.82	0.00
2013-14	3.85	2.94	2.23	0.65	2.85	0.65	19.20	0.00
2014-15	4.00	0.50	2.91	1.00	3.30	0.70	20.87	0.00
2015-16	9.00	10.76	4.50	16.50	4.00	2.00	27.48	9.79
2016-17	9.00	10.48	4.00	22.27	4.00	1.00	27.48	0.00
2017-18	10.00	17.96	6.00	46.00	5.00	0.00	28.31	14.00
Total	**39.98**	**45.21**	**21.64**	**89.64**	**19.60**	**4.35**	**146.16**	**23.79**

(Rs. in crore)

Year	**Hyderabad**		**Kolkata**		**Raebareli**	
	Gen	Cap	Gen	Cap	Gen	Cap
2012-13	15.29	5.00	1.75	-	2.00	1.00
2013-14	15.99	7.00	4.00	0.40	3.00	1.50
2014-15	9.66	4.50	4.00	0.37	4.45	0.00
2015-16	25.00	10.00	5.00	1.30	5.50	0.00
2016-17	25.00	10.00	5.00	3.00	5.50	0.75
2017-18	25.00	5.00	8.00	3.50	8.50	2.00
Total	**115.94**	**41.50**	**27.75**	**8.57**	**28.95**	**5.25**

Total GIA General (incl. GIA Salary for NIPER Mohali) from 2012-13 to 2017-18 = Rs. 400.02 cr.

Total GIA Capital from 2012-13 to 2017-18 = Rs. 218.31 cr.

Funds under General head are provided for recurring expenditure like salary, stipend. Office expenses etc.

Funds under Capital head are provided for creation of capital assets – construction of campus, purchase of equipment & machinery

(Ref: Reply to Q No39)

4.14 During study visit of the Committee in 2017, NIPER Mohali in their written replies has raised the issue of paucity of fund which is hampering their R&D activity. According to them as per recommendation of the Standing Committee on Finance (SFC), a fund of Rs. 249.455 crores were sanctioned for the institute during the 12th Five Year Plan period. But they had received only Rs. 9.79 crores. As a result the following activities NIPER Mohali have been held up:-

(i) A need for R&D facility to carry out research and to undertake high end specialized research in future is a necessity.
(ii) Construction of additional lecture halls to meet the increased requirements of students.
(iii) To make the Dosage Plant functional, main core pharma machinery needs to be procured and finishing touches to the building provided to suit their installation and functioning.
(iv) There is a huge demand of refrigerated water supply and cold storage for research purpose.

It was also stated by the NIPER in their reply two research projects i.e. (i)Tuberculosis (TB) and (ii) Leishmaniasis (kala Azar), were sanctioned for funding by the Department of Pharmaceuticals. The total cost of the projects was Rs. 9.76 crores (Rs. 4.88 crores each). Till date, Rs. 4.88 crores (Rs. 2.44 crores each) has been received by the Institute. The Institute has requested for extension of the project tenure by two years and release of the sanctioned amount for completion of the project objectives.

(Ref: NIPER written Replies Pg No-3 and 4)

4.15 On the above issue the Committee sought the comments of Department of Pharmaceuticals, the latter in its written reply stated as under:-

"After evaluation of TB and Kala Azar projects by an expert committee consisting of external experts, the duration of the projects has been extended by one year up to 31st March, 2019 and additional Rs.2.50 cr. released during the financial year 2017-2018.
Standing Committee on Finance (SFC) had approved Rs. 249.455 crores for the institute during the 12th Five Year Plan period. Out of which, Rs. 9.79 cr. was released to NIPER Mohali during FY 2015-16 for various schemes. However, an amount of Rs. 5.40 cr. remained unspent with them. On request of NIPER, Mohali, the Department has re-appropriated the funds so that it can utilize the same. Further, the Department released additional funds to the tune of Rs. 14.00 crore, as per the priority indicated by the Institute."

(Ref: Reply to Q No-22)

4.16 Further the Committee asked about details of R&D on Kala Azar and Anti TB Agents along with details of BE, RE and actual expenditure on this scheme since its inception and physical targets achieved under this scheme, the Department in its written note stated as under:-

"An amount of Rs. 7.38 crore has been released for Kala Azar and Anti TB Agents since inception of the both projects. The physical targets achieved are as under:

(i) Anti TB

- Molecular docking studies for ICL
- Synthesis of 260 ICL inhibitors
- Synthesis of 164 Malate Synthase Inhibitors
- Biological evaluation of some ICL and MS inhibitors carried out/in progress
- 162 compounds tested by enzyme assays for ICL (90) and MS (72)
- Homology model developed for ATP Synthase
- Synthesis of 170 ATP Synthase Inhibitors
- ATP Synthase inhibitor screening in progress
- Cell based (macrophage) assay initiated

(ii) Kala Azar

Till date approximately 400 compounds have been screened for the antipromastigote activity and the ones which showed better or similar activity to standard drug miltefosine were subjected to cytotoxicity assay. The two targets proposed (Ribose 5-phosphate isomerase B and trypanothionereductase) were cloned from Leishmaniadonovani and expressed to make recombinant protein. Independent enzyme assays were set up for the two targets. Till date compounds have been designed and synthesized based on trypanothionereductase (TR) enzyme."

(Ref: Reply to Q No-23)

4.17 The Committee also asked about the constraints faced during implementation of this scheme and effective steps that are being taken to address these constraints, the Department in its written note stated as under:-

"After evaluation of both the projects by an expert committee consisting of external experts, the duration of the projects has been extended up to 31st March, 2019 and Rs.2.50 cr. released during the financial year 2017-2018."

(Ref: Reply to Q No-24)

4.18 The Department of Pharmaceuticals in their background material has stated that NIPER Mohali had not been allocated any fund for the financial year 2016-17 as they did not utilize earlier funds already allocated. Hence no budgetary allocation has been made in 2017-18.

4.19 The same issue was highlighted during oral evidence of the Department before the Committee and the Secretary Department of Pharmaceuticals clarified on this issue of underutilization by NIPERs which is as under:

"...Till the time the NIPERs do not submit their utilization certificates, we cannot release new installment of funds to them"

(Ref: Proceedings Pg No-17)

4.20 On being asked about the reasons for under utilization of funds which was released prior to 2016-17, the Department in its written note stated as under:-

> "NIPER Mohali could not utilize the funds released in 2015-2016 due to lack of regular Director and absence of re-appropriation. A regular Director has since been appointed and the funds re-appropriated, which would soon be utilized."

(Ref: Reply to Q No-34)

4.21 When the Committee asked whether other NIPERs also showed under utilization of funds, the Department in its written note stated that during recent time, funds released to other NIPERs have been fully utilized.

(Ref: Reply to Q No-35)

4.22 While deposing before the Committee during oral evidence on 11.04.2018 the Adviser/Scientist G from Department of Biotechnology informed about Pharma Mission as under:

> *"We do not have per se any division on pharmaceuticals. But we are working on pharmaceuticals in different areas across DBT. We have launched a major mission which is a pharma mission. Apart from that, I am sure in all these NIPER research, some part will be funded by Department of Bio Technology. So, most of the funding of these projects will be from Department of Bio Technology. We do not categorise that we have to fund only DBT institutes. We fund DBT, DST, CSIR, NIPER and even industry and academi. Wherever good research is required, we fund that. In 2017 there was a Cabinet approval for a major pharma mission which has been launched in 2017. It is a R.1,500 crore Pharma Mission which is headed by the* Biotechnology Industry Research Assistance Council (*BIRAC) along with World Bank. Rs.750 crore would be funded by BIRAC and return would be given by World Bank later on. It has four phases. For R&D, Infrastructure Development Staff and Technical Expertise, Skill Development and creation of enhancing technology transfer. In the first phase we have started R&D proposal; 125 proposals have been received by BIRAC; and 16 have been shortlisted. This is another Mission which will work. We also have a Bio Design Programme because bio-design and bio-devices is an area in which we require expertise of medical doctors and engineer and basic scientists. So, we started a programme about a few years back in collaboration with AIIMS Delhi and IIT Delhi. That programme was very successful.... "*

(Ref: Verbatim Proceedings Pg No-7 & 8)

(C) ACADEMIA- INDUSTRY LINKAGE STATUS

4.23 NIPERs have undertaken 21 Academia - Industry Linkage MOUs with leading pharma industries which include one each with 4 Pharma CPSEs i.e. Rajasthan Drugs and

Pharmaceuticals Ltd (RDPL), Indian Drugs & Pharmaceuticals Limited (IDPL), Karnataka Antibiotics & Pharmaceuticals Limited (KAPL) and Hindustan Antibiotics Limited (HAL) and 2 with Bengal Chemicals and Pharmaceuticals Limited (BCPL) and 15 leading Private Pharma Companies like Dr. Reddy's Labs, Bharat Biotech, NATCO, Cadila Pharmaceuticals, Cadila Healthcare (Zydus), Sahjanand Technologies, Johnson & Johnson, Sun Pharma, Wockahardt, Panacea Biotech and Medley Pharmaceuticals Ltd, Dow Chemical's International Pvt. Ltd., Tirupati Medicate Ltd, Kwality Pharmaceuticals Ltd. and Celeste Life Science Pvt. Ltd. This is Pharma initiative to build Innovation Ecosystem in India.

4.24 While furnishing the outcome of Academia - Industry Linkage MOUs with leading public sector undertakings and private pharma companies, the Department in its written note stated as under:-

> "NIPERs have signed MoUs with various PSUs and private pharmaceutical companies relating to collaborative research programmes in the areas of novel drug delivery, new drug discovery, pharmaceutical product development etc. Along with the research activities, several knowledge-sharing sessions such as workshops and conferences are organized.
>
> In case of NIPER Mohali, zinc sulphate dispersible tablets have been marketed by IDPL; two formulations were commercialized by Promed Exports (now called -SentissPharma) and two formulations were marketed by Montajat Veterinary, Saudi Arabia. Promed and Montajat had sponsored projects at the Institute. NIPERs have over all licensed seven technologies/patents to various Industry partners. Two formulations based on NanoCrySP technology are under commercialization. NIPER Kolkata is undertaking collaborative research activities in identified areas such as Repurposing of existing pharmaceuticals, Novel small molecules for anti-diabetics and drug resistant tuberculosis, API by synthetic biology/ cell factory, phyto-pharmaceuticals, rare diseases of public health importance etc. Academia-Industry MoUs of NIPERs have led to collaborative research, student training, joint publications, joint patents, joint conferences and symposiums. Technology has been transferred in many cases."
>
> **(Ref: Reply to Q No-30)**

4.25 On being asked about the details of feasibility of constituting a consortium of pharma companies both public and private to pool their resources to invest for R&D activities, the Department in its written note stated as under:-

> **"** In principle, it is feasible to constitute a consortium of pharma industries for investing in R&D. However, the Government has already decided to either close or strategically sell all the pharma CPSUs."
>
> **(Ref: Reply to Q No-31)**

4.26 During same oral evidence before the Committee, the Secretary Department of Pharmaceutical gave following views on Academia -Industry link:-

"*...Quarterly conferences where coordination can be done, that we have done these many researches, now for commercial conversion we have to work with industry and find a link with research. We have to address concerns of industry and research...interaction with industry is not continuous, researchers are scientific people they can work in labs but they cannot sell like marketing agents...we need to convince industry about the worth of these research works but there is no platform to link both of these*"

(Ref: verbatim Proceeding Pg No-6 & 7)

(D) COMMERCIALIZATION OF RESEARCH STATUS

4.27 While submitting before the Committee during oral evidence on the Subject on 11.04.2018 the Secretary Department of Pharmaceuticals gave following views on commercialization of research in NIPERs:

" Every NIPER is doing something or other research. Similarly various CSIR labs might be doing something new. ICMR projects are doing their new research. But they do not get converted into commercial activity.....its not that companies are not coming, but we are not able to reach to the company's "

(Ref: Verbatim Proceeding Pg No-5)

4.28 Elaborating on the mechanism available and efforts made by the Government to convince and incentivize private/public/joint venture pharmaceutical companies to undertake commercial production of new drug formulations discovered by various R&D Institutions including NIPERs, the Department in its written note stated as under:-

"There is no specific mechanism to incentivize the Pharma companies to undertake commercial production of new drug formulations discovered by various R&D Institutions including NIPERs. However, the Department of Pharmaceuticals is in the process of facilitating the Pharma Industry to undertake commercial manufacture of bulk drugs including those based upon the discoveries/technologies developed by R&D Institutions including NIPERs."

(Ref: Reply To Q No-41)

4.29 On being asked about the steps being taken/proposed to be taken for commercialization of research done by NIPERs under the administrative control of Ministry, the Department in its written note stated as under:-

"NIPERs are at the initial stage of research, except NIPER Mohali. The Institute is under process to collaborate with National Research Development Corporation (NRDC) to facilitate the commercialization of existing patents of NIPER."

(Ref: Reply To Q No-40)

4.30 Further, on being asked about the reasons for not being able to make any significant molecular achievement/discovery indigenously, the Department in its written note stated as under:-

> "NIPERs are under initial phases of establishing research infrastructure, own regular campus and laboratories, regular faculty and scientific staff. These are some of the crucial aspects which need to be addressed for success in drug discovery process."

(Ref: Reply to Q No-26)

CHAPTER-V

CHALLENGES & CONSTRAINTS BEING FACED BY THE DEPARTMENT

The Department enumerated the main Challenges & Constrains as under:-

1. Though the Department is dealing with the high technical aspects of research, the R&D division of the Department does not have any technical experts, as found in Department of Health and Family Welfare, MHRD, DST, SBT, CSIR, ICMR and like others.
2. The premier higher of education and research institutions on Pharmaceuticals Sciences-National Institutes of Pharmaceutical Education and Research (NIPERs), though 7 NIPERs are operating, only one i.e , NIPER, Mohali is full-fledged with its own campus and sanctioned faculty, while all other NIPERs are running from temporary accommodation/mentor institutions for the last 8 years. Thus undertaking of research by contractual and adhoc faculty can be expected. Even at Mohali, the faculty is not at full sanctioned strength because of inadequate budgetary allocations.
3. No/poor budgetary allocation for Department of Pharmaceuticals, especially for the research.
4. Pharmaceutical Sciences is a multi-disciplinary science and is spread over a large number of Ministries and Departments viz., Department of Biotechnology, Department of Science and Technology, Council for Scientific and Industrial Research, Indian Council for Medical Research, Department of Health and Family Welfare, Ministry of Human Resource Development, Department of AYUSH, and others. The Coordination/Convergence require adequate and competent manpower, which are not available with the Department of Pharmaceuticals.
5. Drug Discovery/Pharma research and development involves high investment involving high risk.
6. Private Sector should also be actively engaged in the exercise of making India a global hub for Drugs Discovery while pursuing all components viz., investment, regulatory practices, intellectual property rights, quality manpower etc., required for achieving the same.

(Ref: Pg No-1 and 3 of Background Note)

A <u>Coordination and Cooperation with Pharma Companies</u>

5.2 The Committee asked the Department the way they are going to address the challenges of drug discovery and pharma innovation hub with this limited budgetary allocation, the Department in its written note stated as under:-

> "Through partnership with pharma companies and by joining the core competencies of NIPERs and initiating funding schemes specific to local pharmaceutical needs, the Department hopes to overcome drug discovery challenges."

(Ref: Reply to Q No-25)

5.3 On being asked what prevents the Department to appoint technical experts in R&D Division of the Department of Pharmaceuticals, the Department in its written note stated that there is no separate R& D Department. NIPERs act as research arm of the Department.

(Ref: Reply to Q No-36)

5.4 Further the Committee also asked about the role and functions of R and D Division of the Department and steps the Department is taking to address the shortage of technical experts, the Department in its written note stated as under:-

> **"**The role & functions include promotion and coordination of basic, applied and other research in areas related to Pharmaceuticals sector. It also includes education and training including high end research and inter-sectoral coordination including coordination between organizations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department.Inadequate budget allocation for all the NIPERs is main reason for lack of academic and non-academic personnel and world class equipment."

(Ref: Reply to Q No-37)

5.5 During oral evidence of the Department on the subject on 11.04.2018, the Secretary Department of Pharmaceuticals submitted following views on challenges faced by the Department:

> *"Presently Drug Discovery job is being done at different places. You can say the coordination is in books, but the fact is that there is no specific coordination mechanism for example we do not know what is being done in NIPERs is being done in CSIR lab, isn't it duplication, though there is no harm in it because which hits first is better. But still there is no common platform where we can share information with each other. Group of Secretaries suggested that his must be but could not be taken forward. I suggest, in case, this committee direct, I am ready to take lead, one inter-departmental Committee may be constituted to at least organize and direct research work.*

(Ref: Verbatim Proceeding Pg No-5)

(B) <u>Public/Consumer Awareness</u>

5.6 While furnishing before the Committee about the initiatives the department has taken to disseminate the new drug discoveries/innovations/formulations for the awareness and education of industry, the Department in its written note stated as under:-

> "DoP regularly funds conferences, symposia and workshops to publicize research findings. NIPERs also encourage their faculty to publish their scientific reports in high impact journals for dissemination to broader audiences."

(Ref: Reply to Q No-42)

5.7 The Committee further asked about the details of mechanism the government have or proposed to have to bring wide publicity and transparency regarding the expiry of important drugs/medicines to the pharmaceutical industry and other stakeholders, the Department in its written note stated as under:-

> **"**The Department is implementing a scheme Pharmaceutical Promotion Development Scheme (PPDS) through which it is partly financing conferences/ seminars for updating the industry/stakeholders of the requirements of the country and global opportunity/need."

(Ref: Reply to Q No-43)

5.8 Further the Committee also asked about the government proposing any legislation to make generic medicine prescription mandatory for government doctors, the Department in its written note stated asunder:-

> "Ministry of Health and Family Welfare (Directorate General of Health Services) have vide their Order No. S-11025/45/10-MH-I dated 26/05/2010 instructed Central Government Hospitals to provide only good quality generic medicines and whenever any branded drug is prescribed, it shall invariably also be mentioned that any other equivalent generic drug could also be provided."

(Ref: Reply to Q No-44)

(C) <u>FUTURE PHARMACEUTICAL RESEARCH</u>

5.9 The Committee also asked about the strategy that is being adopted by the Department of Pharmaceuticals and NIPERs for producing biological drugs instead of chemical drugs, benefits of biological drugs over chemicals drugs, the Department in their written note stated as under:-

> "Biologics, also called biopharmaceuticals, have revolutionized vaccination programs, treatment in chronic and serious illnesses like rheumatoid arthritis, cancers, diabetes, etc., and nudged traditional drugs out of the top slots, with sales increasing year after year. Chemically, biologics are complex protein molecules manufactured using recombinant DNA methods and live organisms. Biologic drugs have been playing significant role in meeting the unmet medical needs particularly in the field of non-communicable diseases including diabetes, autoimmune and various types of cancer diseases etc.
>
> Biologic drugs are basically protein in nature which differs from the conventional chemical drugs in many aspects. The biologic drugs are produced using living organisms or cells in combination with recombinant DNA technology. These biologic include therapeutic monoclonal antibodies, Insulin, Filgrastim, Erythropoietin, Interferon, fusion proteins, hormones and subunit vaccines, human blood products including albumin, intramuscular and intravenous immunoglobulin, coagulation factor VIII and IX etc. In general, the cost of setting a manufacturing facility of r-DNA derived biosimilar varies from US$ 100 to 250 million and takes 7-8 years to develop the drug whereas the cost of setting up a generic chemical drug facility varies from US$ 2-3 million and takes ~2-3 years for the development of the drug.
>
> The Government of India is committed to provide affordable health care to all and recognizes the prospects of biologics and biosimilars in disease treatment. The Government

has taken several steps in widening the range of biologic drugs production through encouraging cooperation between academics, industries and regulators. However, considering the cost- efficacy, Indian biopharma industry is investing mainly in similar biologics/biosimilar product development which would be beneficial to a large number of patients in India due to its affordability and accessibility. According to Central Drugs Standard Control Organization (CDSCO) and the Department of Biotechnology (DBT) a Similar Biologic product is that which is similar in terms of quality, safety and efficacy to an approved Reference Biological Product based on comparability.

The Indian biosimilar market is poised for big growth, augured by the launch of new products, growing acceptance of biosimilars and the entry of new players. Development of biosimilars is dependent on significant investments, not only in terms of high costs associated with long term and unpredictable research and also the time consuming series of trials followed by regulatory approvals.

India has an efficient and well-coordinated regulatory approval and marketing system duly synchronized with global guidelines available on biosimilars. The Review Committee on Genetic Manipulation (RCGM), Department of Biotechnology authorizes the conduct of research and development, exchange of genetically engineered cell banks for the R & D and review of data up to preclinical evaluation in the country. Once recommended by the RCGM, the proposal of biologic drug is sent to Drug Controller General (India) (DCGI) for appropriate clinical trials and market authorization. Further, DBT and CDSCO have revised the Guidelines of 2012 to "Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India in year 2016" for the harmonization with other global guidelines available on Biosimilars.

Accordingly, RCGM has assessed and recommended 64 biosimilar biological molecules on average 9 products / year to DGCI for clinical trials. As per Generic and Biosimilar Initiative (GaBI) journal 2017, India has produced 27-28 similar biologic/biosimilar version of branded/reference biologic drug at reasonable cost and these are accessible to the patients suffering from various cancers and autoimmune diseases etc.

Recognizing the prospects of biological drugs, under Pharmaceuticals Promotion and Development Scheme (PPDS) of Department of Pharmaceuticals a series of seminars are planned on various aspects of the subject "Promoting growth of Biological Sector in India" for the year 2018-19."

(Ref: Reply to Q No-45)

5.10 While submitting before the Committee during oral evidence on the subject on 11.04.2018, the Secretary Department of Pharmaceuticals gave following views on upcoming research in Pharmaceuticals:

"... now our focus is going on biologics... in which not chemical medicine but gene based or microbe base biological medicines are inserted inside the body for treatment. It is estimated that after five to seven years fifty percent of medicines will be biologics based...we have to take this knowledge to industry because those industries which are making chemical based medicines we have to incentivize them to go towards biologics based medicine, will have to change their mindset. This is going at slow pace but now there is need to accelerate its pace."

(Ref: Verbatim Proceedings Pg No 19)

PART II

RECOMMENDATIONS/OBSERVATIONS

RECOMMENDATION NO. 1

Post -WTO AND TRIPS - Challenges before Pharmaceutical Research and Development Indian Industry

India is globally considered the third largest producer of medicines by volume and the fourteenth in terms of value because of the fact that Indian medicines are among the lowest price in the world. India exports medicines to more than 200 countries and earns revenue more than Rs. 1,00,000 crore. Out of the total, production 50% medicines are consumed in the country itself and rest 50% are exported. This export of medicines is reckoned with third largest export sector in the country after gems & jewellery and textile sectors. The Committee note that this robust growth has taken place due to low cost manufacturing and skilled manpower. However, the Committee note that India had to make a paradigm shift in their pharmaceutical policy in the backdrop of post-WTO and TRIPS agreement in the mid nineties. The country had to move from process patent regime to product patent regime by amending the Patent Act 1970 in 2005.

Under the TRIPS Agreement, WTO Members have to provide patent protection for any invention, whether a product or process for atleast 20 years from the date on which the patent application was filed. This issue reiterated the urgency for India to have paradigm shift in its strategy to expand its leadership in Drug Discovery and Innovation. The Committee also note that the global pharmaceutical industry is shifting from chemical based medicines to biologics based medicines.

The Committee note that the Department of pharmaceuticals in their pursuit to strengthen pharmaceutical invention and discovery, commissioned a Detailed Project Report for Developing India as a Drug Discovery and Pharmaceutical Innovation Hub presented by the firm - Ernst & Young, which highlights that India has emerged as a potent drug development service provider but not a key player in innovative product research. Indian bio-pharmaceutical companies are in early stage/biological research and translational research capabilities and R&D funding are weak compared to global bio-pharmaceutical companies. The Committee note that the contribution of Indian academia to new drug research is not substantive and as a result patents and publishing have not translated into licenses due to poor and inadequate alignment with private sector.

The Committee further note that pharmaceuticals sector in India is a multi-disciplinary and the research is spread across a large number of Ministries/Departments viz., Department of Biotechnology, Department of Science and Technology, Council for Scientific and Industrial Research, Indian Council for Medical Research, Department of Health and Family Welfare, Ministry of Human Resource Development, Ministry of AYUSH, and others.

In view of the aforesaid challenges both from internal and external environment, the Indian pharmaceutical Industry faces an uphill task to sustain their growth momentum in the backdrop of WTO and TRIPS regime. The Committee are of the considered view that to manufacture medicines at affordable prices for poor people in the country, it becomes quite imperative to

revisit and explore the pharmaceutical regime by way of readjusting the existing policy and frame work of rules and regulation in the backdrop of requirements/commitments of WTO and TRIPS on priority to neutralize would be negative impact on the Indian Pharma industry. The Committee also desire that the action taken on the report submitted by the firm - Ernst & Young be expedited and the former be apprised of the steps taken in this regard.

RECOMMENDATION NO. 2

Need for Institutionalized Inter-Departmental Coordination Mechanism

The Committee note that to give boost to the pharma education and research, the Government created a separate Department i.e. Pharmaceuticals under the Ministry of Chemicals and Fertilizers in 2008 with the mandate to formulate pharma policy, planning, development and regulation of pharmaceuticals industries excluding those falling under the administrative control of other Ministries/Departments. The Department was also allocated to look after Inter-sectoral coordination including coordination between organizations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department. The Committee are unhappy to note that there has been no inter-sectoral or inter-departmental coordination strong enough to put the mandate in proper perspective.

The Committee further note that pharmaceutical research is spread over a large number of Ministries/Department like Department of Biotechnology, Department of Science and Technology, Council for Scientific and Industrial Research, Indian Council for Medical Research, Department of Health and Family Welfare, Ministry of Human Resource Development, Ministry of AYUSH and others. This scattered pharmaceutical research involves lot of overlapping and duplication of research projects ultimately leading to wastage of rare national resources allocated to different stakeholders. The Department also shared and endorsed the view of the Committee in this regard during their deposition before the Committee. The Department agreed with the proposal of the Committee for a separate inter-departmental Committee to be headed by the Secretary,

Department of Pharmaceuticals to ensure no overlapping and duplication of efforts and resources and to conduct research in a collaborative, synchronized and synergized way for optimum utilization of funds allocated in this regard.

In view of the above, the Committee after having examined the subject in its entirety are of the strong view that there is an emergent need to institutionalized a robust mechanism of inter-departmental coordination in the Government to ensure economy, efficiency, effectiveness and transparency in the arena of Pharmaceutical research. The Committee further suggest that the budget allocation and any umbrella/National flagship scheme(s) to the pharma education and research be finalised by the Government only after consulting with this proposed inter-departmental mechanism.

The Committee also note that Ministry of Finance, Department of Expenditure vide their OM. No. 24(35)/PF-II/2012 dated 05.08.2015 had instructed for rationsalisation of schemes which are to be implemented by various Ministries.

Subsequent to this instruction, the Department of Pharmaceuticals had proposed an umbrella Scheme for Development of Pharmaceuticals industry. While expressing their satisfaction over such instruction of Ministry of Finance, the Committee are of the view that much is needed to be done to streamline and consolidate, the R&D activities by different organizations/institutions.

RECOMMENDATION NO. 3

Linkage between Academia and Pharmaceuticals Industry

The Committee note that a separate Department for pharmaceuticals was created in 2008 under the Ministry of Chemicals and Fertilizers with the mandate of policy, planning, development and regulation of pharmaceuticals industries excluding those specifically allotted to other departments. The subject - promotion and coordination of basic, applied and other research in areas related to the pharmaceutical sector was allocated to the newly created Department of Pharmaceuticals.

The Committee notice that the Department of pharmaceuticals set up 07 NIPERs under NIPER Act 1998 to boost pharma education and research other than the mandate of policy, planning, development and regulation of pharmaceuticals industries. The Committee have been apprised that these NIPERs have undertaken 21 Academia - Industry Linkage MOUs with leading pharma industries which include one each with 4 Pharma CPSEs i.e. Rajasthan Drugs and Pharmaceuticals Ltd (RDPL), Indian Drugs & Pharmaceuticals Limited (IDPL), Karnataka Antibiotics & Pharmaceuticals Limited (KAPL) and Hindustan Anti-biotic Limited (HAL) and 2 with Bengal Chemicals and Pharmaceuticals Limited (BCPL) and 15 leading Private Pharma Companies in a bid to build Innovation Ecosystem in India. Other than this, NIPERs have signed MoUs with various PSUs and private pharmaceutical companies relating to collaborative research programmes in the areas of novel drug delivery, new drug discovery, pharmaceutical product development etc. along with the research activities, several knowledge-sharing sessions such as workshops and conferences.

The Committee were informed that a consortium of pharma industries for investing in R&D is a feasible option but the Government has already decided to either close or strategically sell all the pharma CPSUs. There is no specific mechanism to incentivize the Pharma companies to undertake commercial production of new drug formulations discovered by various R&D Institutions including NIPERs in the country. The Committee notice that however, the Department of Pharmaceuticals is in the process of facilitating the Pharma Industry to undertake commercial manufacture of bulk drugs including those based upon the discoveries/technologies developed by R&D Institutions including NIPERs but the inadequate link between industry and academia has been a stumbling block in commercialization of the research work done in pharma academic institutes i.e. NIPERs.

The Committee strongly feel that there is an urgent need to convince the pharma industry about the efficacy, safety and effectiveness of research by way of reaching out to the pharma industry. Therefore, taking a holistic view of the subject, the Committee strongly recommend to create a common platform for exchange of ideas on present and future pharma research needs of country and the necessary mutual corporation between pharma industry and academia to jointly look at feasibility of converting research into commercial products.

RECOMMENDATION NO. 4

Need to boost Infrastructure for Pharmaceutical Research and Development under NIPERs

The Committee note that the government has set up National Institutes of Pharmaceutical Education and Research (NIPERs) under NIPER Act 1998 as the higher premier institutions of education and research on Pharmaceuticals Sciences. Among these 7 functional NIPERs, at Mohali, Gandhinagar, Guwahati, Hajipur, Hyderabad, Kolkata and Rae Bareilly only one NIPER, Mohali is full-fledged with its own campus and sanctioned faculty, while all other 06 NIPERs are running from temporary accommodation/mentor institutions for the last 8 years. Apart from this, the Committee find that these NIPERs are run by contractual and adhoc faculty. Even at Mohali, the faculty is not at full sanctioned strength because of inadequate budgetary allocations.

Further, the Committee also note that in absence of Board of Governors, Steering Committee under chairmanship of Secretary, Department of Pharmaceuticals looks after administrative/financial matter of NIPERs on adhoc basis and the posts of Directors, NIPERs Hajipur and Hyderabad are still to filled up. Lack of permanent campuses, well-equipped-laboratories, permanent faculty and staff and insufficient funding are some of the critical constraints which are considered a stumbling block to accomplish the academic and research agreed upon under MOUs with pharma industry.

The Committee were informed that a meeting of Expenditure Finance commission (EFC) held under the chairmanship of Secretary, Expenditure,

Ministry of finance on 26.03.2018 has given its recommendations for providing infrastructure support, creation/filling up of posts etc. for existing NIPERs. Subsequent to the approval of the EFC action is being initiated for creation of academic and non-academic posts and appointment of regular faculty will rescue the attrition brain drain from these NIPERs.

The Committee having taken the requisite infrastructure like, building, state of the art labs and regular talented faculty into account as sacrosanct for pharmaceutical academics and research, strongly recommend to holistically address constraints concerning infrastructure, governance and human resource and make comprehensive strategy to boost pharmaceuticals research and development base of the existing NIPERs. The Committee also recommend the Department to pursue the cause of adequate budget with Ministry of Finance and to coordinate with the allied Ministries/Department like DBT/CSIR/ICMR etc to get funds for NIPERs research projects.

Further, the Committee also suggest that Department to look into feasibility of creating two separate Departments i.e. academics and research with respective Head of Department under the Director of the Institute so that both the disciplines may be given due priority.

RECOMMENDATION NO. 5

Need to enhance budget allocation for Pharma Research and Development

The Committee note that new Schemes for Assistance to Bulk drugs industry for Common Facilitation Centre, Assistance to Medical device Industry for Common Facilitation Centre, Cluster Development, Pharmaceuticals Technology Up-gradation Assistance Scheme (PTUAS) and Pharmaceuticals Promotion Development Scheme (PPDS) are proposed to be taken up for promoting the growth of Pharmaceutical and Medical Device Industry which came to fore after the instruction of Ministry of Finance on 5 August, 2018. But the Committee observe with dismay that no allocation for all these heads has actually been made by the Department of Pharmaceuticals. As such the Committee strongly recommend to allocate specific amount for all the schemes for the promotion of R&D as well as for the growth of Medical Device industry.

The Committee further noticed that there is no centralised mechanism to ensure no overlapping of research efforts takes place, which is prevailing at present. The Committee desire that pharmaceutical research be conducted in a synchronised and synergised way.

The Committee note that the expenditure incurred by NIPERs has been Rs. 400.02 crores under Grant-in-Aid-General provided for recurring expenditure like salary, stipend, office expenses etc from 2012-13 to 2017-18. The Grant-in-Aid-Capital has been Rs. 218.31 crores provided for creation of capital assets – construction of campus, purchase of equipment & machinery during the period 2012-13 to 2017-18. The Committee also note that Standing Committee on Finance (SFC) recommended a fund of Rs. 249.455 crores for NIPER Mohali alone

during the 12th Five Year Plan period but they had received only Rs. 9.79 crores. The Department submitted the reason before the committee that till the Institutes do not submit their utilization certificate they cannot release new funds.

The Committee have noticed that one of the major challenges is that the Budget allocations made for Research and Development are thinly spread over many Ministries/departments/schemes and therefore the high capital needs of the pharmaceutical Research and Development are not adequately addressed to and as result, no tangible output is achieved. The Committee, therefore strongly recommend that there is need to develop innovation and research base of pharmaceuticals sector in India and for that robust budgetary support to Research and Development in pharmaceutical sector by making a separate head for Research and Development under budgetary allocation be made to Department of pharmaceuticals.

RECOMMENDATION NO. 6

Future Pharmaceutical Research

The Committee were apprised by the Department of Pharmaceuticals that Biologics also called Biopharmaceuticals have revolutionized vaccination programmes, treatment of chronic and serious illness like Rheumatoid arthritis, cancers, diabetes etc. and nudged traditional drugs out of top slots. Biologic drugs have been playing significant role in drugs have been playing significant role in meeting the unmet medical needs particularly in the field of non-communicable diseases including diabetes, auto-immune and various types of cancer disease etc.

The Committee are given to understand that a lot of deliberation has been made for the promotion and growth of R&D in Biologics, but still no headway has been made in the country. In India where people are badly affected by diabetes and cancer patients are increasing day by day with no much effective treatment, the Biologics is the need of hour. As such the Government should earmark a separate fund for the promotion and growth of Biologics. As submitted by the Secretary, Department of Pharmaceuticals, before the Committee that after five to seven years fifty percent medicines will be Biologics based, it is imperative that attention to R&D activities on Biologics be made in coordination with all the research organizations and industries.

New Delhi;
July, 2018
Ashadha, 1940 (Saka)

ANANDRAO ADSUL
Chairperson
Standing Committee on
Chemicals and Fertilizers

APPENDIX 1

MINUTES OF THE TENTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS

(2017-18)

The Committee sat on Wednesday, the 11th April, 2018 from 1500 hrs. to 1700 hrs. in Committee Room 'E', Parliament House Annexe, New Delhi.

PRESENT
Shri Anandrao Adsul - Chairperson
MEMBERS
LOK SABHA

1. Shri Anandrao Adsul, Chairperson
2. Smt. Anju Bala
3. Shri B. N. Chandrappa
4. Smt. Veena Devi
5. Shri Innocent
6. Shri K. Ashok Kumar
7. Shri S. Rajendran
8. Dr. (Prof.) Azmeera Setaram Naik
9. Dr. Kulamani Samal
10 Dr. Uma Saren
11. Smt. Rekha Arun Verma

RAJYA SABHA

12. Shri Ranvijay Singh Judev
13. Shri B. K. Hariprasad

SECRETARIAT

1. Shri Vinod Kumar Tripathi - Joint Secretary
2. Shri A. K. Srivastava - Director
3. Shri U. C. Bharadwaj - Deputy Secretary

LIST OF WITNESSES

I. MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

1.	Shri Jai Priye Prakash	Secretary
2.	Smt. Meenakshi Gupta	AS & FA
3.	Shri Rajneesh Tingal	Joint Secretary

II. REPRESENTATIVES OF NIPERs

1.	Prof. Kiran Kalia	Director NIPER, Ahmadabad
2.	Dr. Pradeep Das	Project Director NIPER, Hajipur
3.	Dr. V. Ravichandiran	Director NIPER, Kolkata
4.	Dr. U. S. N. Murty	Director NIPER, Guwahati

III REPRESENTATIVES FROM OTHER MINISTRIES/DEPARTMENTS

1	Dr. Ekta Kapoor	Scientist E, Department of Science and Technology
2.	Shri Raj Durai	Scientist D, Department of Science and Technology
3.	Shri Sandeep Sarin	Adviser/Scientist G, Department of Biotechnology
4.	Ms. Rajni Kaul	Scientist G, ICMR, Department of Health Research

2. At the outset, Hon'ble Chairperson welcomed the Members of the Committee and representatives of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) and other officials to the sitting. Their attention was invited to the provisions contained in Direction 55(1) of the Directions by the Speaker regarding confidentiality of the Committee's proceedings.

3. After the witnesses introduced themselves, Directors NIPER Guwahati, NIPER Ahmadabad, NIPER Kolkata and NIPER Hajipur respectively made Power Point Presentation one by one to the Committee on their mandate and activities undertaken by their respective

institutes in respect of education and research in pharmaceutical domain. They also apprised the Committee about various constraints faced by them in R&D activities.

4. Thereafter, Secretary, Department of Pharmaceuticals briefed on the subject "Promotion and Coordination of basic, applied and other research in areas related to the Pharmaceuticals Sector". He also solicited representatives of other departments *viz*. Council of Scientific & Industrial Research (Department of Science & Technology), Department of Biotechnology and Indian Council of Medical Research (Department of Health & Research) to apprise the Committee on the subject.

5. During the discussion, the Hon'ble Chairperson and Members of the Committee raised the following points :-

(i) Ineffective interdepartmental coordination mechanism resulting in duplication of research activities;

(ii) Shortage of funds allocated for NIPERs;

(iii) Absence of industry linkages in research work of NIPERs in particular;

(iv) Absence of common platform to intimate industry about mature research work due to which commercialization of research is getting hampered;

(v) Incentives for private sector to invest in Research & Development;

(vi) Problems related to contractual jobs specially for faculty in NIPERs and Creation of permanent posts of faculty members in NIPERs to check their attrition;

(vii) Review of existing Recruitment Rules for NIPERs, if any, otherwise formulate new Recruitment rules to contain talents;

(viii) Institutional collaboration and an effective mechanism of regular nature needed to promote R& D in pharma sector.

6. The aforesaid concerns/issues raised by the Committee were duly responded by the Secretary Department of Pharmaceuticals and other officials including representatives of NIPERs.

7. The Chairperson thanked the witnesses for appearing before the Committee as well as for furnishing valuable information to the Committee. They were also asked to provide required information not readily available at the earliest.

8. A copy of the verbatim record of the proceedings of the sitting has been kept.

The Committee then adjourned.

APPENDIX II

MINUTES OF THE THIRTEENTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS

(2017-18)

The Committee sat on Friday, the 13 July, 2018 from 1515 hrs. to 1545 hrs. in Committee Room 'B', Parliament House Annexe, New Delhi.

PRESENT
Shri Anandrao Adsul - Chairperson
MEMBERS
LOK SABHA

2. Smt. Anju Bala
3. Shri R. Dhruvanarayana
4. Shri Chhedi Paswan
5. Dr. Kulamani Samal
6. Dr. Uma Saren
7. Dr. (Smt.) Ratna De (Nag)
8. Shri Sarfaraz Alam

RAJYA SABHA

9. Shri Prem Chand Gupta
10. Dr. Sanjay Sinh
11. Shri Vijay Pal Singh Tomar

SECRETARIAT

1. Shri Vinod Kumar Tripathi - Joint Secretary
2. Shri A. K. Srivastava - Director
3. Shri U. C. Bharadawaj - Deputy Secretary

2. At the outset, the Hon'ble Chairperson welcomed the Members of the Committee.

3. The Committee thereafter took up for consideration and adoption the following draft Reports:

(i) Draft Report on the subject 'Promotion and Coordination of basic, applied and other research in areas related to the Pharmaceutical Sector' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)

(ii) Draft Report on Action taken Replies by the Government on the Observations/ Recommendations contained in the Fortieth Report of the Standing Committee on Chemicals and Fertilizers (16 Lok Sabha) on the subject 'Implementation of New Urea Policy - 2015' of the Ministry of Chemicals and Fertilizers (Department of Fertilizers); and

(iii) Draft Report on Action taken replies by the Government on the Observations/ Recommendations contained in the Forty third Report of the Standing Committee on Chemicals and Fertilizers (16th Lok Sabha) on 'Demand for Grants (2018-19)' of the Ministry of Chemicals and Fertilizers (Department of Fertilizers).

4. After deliberations the Draft Reports were adopted by the Committee. without any changes/amendments.

5. The Committee authorised the Chairperson to make consequential changes, if any, arising out of the factual verification of the Reports by the Department of Pharmaceuticals and Department of Fertilizers.

The Committee then adjourned.